EXHIBIT 9

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SUPPLIERS' ACQUISITION COSTS FOR ALBUTEROL SULFATE

JUNE GIBBS BROWN
Inspector General

JUNE 1996
OEI-03-94-00393

EXECUTIVE SUMMARY

PURPOSE

This report examines suppliers' acquisition costs and Medicare allowances for albuterol sulfate, an inhalation prescription drug used in conjunction with nebulizers.

BACKGROUND

Title XVIII of the Social Security Act prescribes coverage requirements under Part B of the Medicare program. Part B covered items and services include durable medical equipment (DME) as well as certain outpatient prescription drugs. The Health Care Financing Administration (HCFA) administers the Medicare program.

Medicare does not generally pay for outpatient prescription drugs. However, there are several exceptions to this general rule, including payment for drugs used in conjunction with durable medical equipment (DME), such as a nebulizer. For such drugs, Medicare computes an allowed amount based on the lower of estimated acquisition costs (EACs) or the median of national average wholesale prices (AWPs).

Medicare allowed amounts for all inhalation drugs remained relatively stable during 1990 through 1992, never exceeding about $78 million annually. In 1993, allowances rose to about $170 million, and climbed to about $227 million in 1994, an increase of almost 200 percent since 1990. During the 14-month period of our review--January 1, 1994 through February 28, 1995--allowances for inhalation drugs totaled approximately $269 million. The subject of this study--albuterol sulfate--accounted for more than $182 million in allowances during the 14-month period.

In this report, we examine Medicare payments for albuterol sulfate compared to suppliers' acquisition costs for the drug. Albuterol sulfate is the most commonly prescribed inhalation drug used for nebulizer therapy. This report is one of a series of Office of Inspector General (OIG) inspections concerning Medicare payments for outpatient prescription drugs in general and inhalation drugs in particular.

FINDINGS

Medicare's allowances for albuterol sulfate substantially exceed suppliers' acquisition costs for the drug.

Suppliers pay an average cost of $0.19 per milliliter (ml) to purchase albuterol sulfate, while Medicare's allowed amounts ranged from $0.40 per ml to $0.43 per ml during the period of our review. Medicare could have saved $94 million during the 14-month period of our review if albuterol sulfate allowances had been based on the average of supplier invoice costs.

Average supplier costs for albuterol sulfate ranged from $0.14 per ml to $0.23 per ml depending on the purchase source. Suppliers purchasing albuterol sulfate directly from a manufacturer paid the lowest average cost, $0.14 per ml. When purchased from wholesalers, suppliers paid an average of $0.20 per ml. Suppliers purchasing the drug from pharmacies paid the highest average cost, $0.23 per ml. Most of the albuterol sulfate billed to the Medicare program was the generic form of the drug.

RECOMMENDATIONS

The findings of this report indicate that Medicare's allowances for albuterol sulfate substantially exceed suppliers' costs for the drug. During the period of our review, Medicare reimbursed suppliers at allowed amounts ranging from $0.40 to $0.43 per ml of albuterol sulfate. These allowances were based on drug manufacturers' AWPs. Current HCFA regulations allow Medicare reimbursement to be based on the lower of EAC or median AWP. However, HCFA has been unsuccessful in obtaining the data to determine EAC.

We believe our invoice cost analysis further supports the recommendation made in an earlier OIG report entitled *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390). In that report, we suggested various options and recommended that **HCFA should reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments for prescription drugs.** Options included a discounted wholesale price, manufacturers' rebates, competitive bidding, inherent reasonableness, and acquisition cost. For our readers' convenience, we have included the full text of these options in the Recommendation section of this report.

HCFA COMMENTS

The HCFA concurred with our recommendation. In exploring new strategies for changing Medicare's payment for prescription drugs, HCFA has constructed a framework to calculate drug prices centrally. They are also reviewing other approaches that could improve Medicare drug reimbursement. For the complete text of HCFA's comments, see Appendix D.

OIG RESPONSE

We support HCFA's efforts to revise its drug reimbursement mechanisms to more appropriately pay for prescription drugs covered under the Medicare program. We believe revisions to the current payment methodologies that take into account the actual costs of these drugs would provide significant savings to the Medicare program.

TABLE OF CONTENTS

PAGE

EXECUTIVE SUMMARY

INTRODUCTION 1

FINDINGS 6

- Medicare's allowances exceed suppliers' acquisition costs 6

RECOMMENDATIONS 9

APPENDICES . . . . .

A: Nonrespondent Analysis A-1

B: Cost Estimates and Confidence Intervals B-1

C: Calculation of Potential Medicare Savings C-1

D: Agency Comments D-1

drug to the beneficiary, (3) description of the drug provided, and (4) drug procurement costs and related drug costs. We asked suppliers to submit copies of documents from their files, such as physician prescriptions, invoices showing drug procurement costs, and beneficiary medical information, to support each sampled J7620 claim.

Supplier Response Rates

Suppliers returned completed requests for 418 of the 485 sampled J7620 claims (86 percent response rate). Some respondents did not, however, submit copies of all of the claim-supporting documentation that we requested. We contacted these suppliers by telephone and letter to secure missing documentation. After executing this follow-up plan, we achieved a 47 percent overall response rate for claim-supporting albuterol sulfate invoices. However, invoice response rates varied widely by strata. These strata response rates are presented in Appendix A.

Nonrespondent and Invoice Cost Analyses

As mentioned above, a 47 percent response rate for claim-supporting invoices was achieved. To address the potential bias effects that suppliers who did not provide albuterol sulfate invoices may have had on our cost estimates, we conducted a chi-square analysis of nonrespondents (a statistical method used to test a hypothesis between observed and expected results). Chi-square analysis indicates that there is a significant difference between suppliers who provided invoices and those who did not provide invoices with respect to asset size. Suppliers in our sample possessing assets in excess of $100 million were less likely to submit invoices to support their albuterol sulfate claims. The table in Appendix A shows that only 5 percent of claims billed by suppliers owning assets over $100 million were supported with invoices. In contrast, invoices were submitted for 61 percent of claims billed by suppliers owning assets under $100 million.

Cost estimates were computed based on a sample of claim-supporting invoices for albuterol sulfate submitted by supplier respondents. (Cost estimates and associated confidence intervals appear in Appendix B.) However, our calculations may overestimate average supplier invoice costs. As explained above, there is a relationship in our sample between suppliers' submission of invoices and the size of their assets. We believe large suppliers owning assets over $100 million may be able to use their market power to negotiate low costs for albuterol sulfate with drug manufacturers, wholesale outfits, and pharmacies.

The overall estimate of average supplier cost for albuterol sulfate was applied to a conservative calculation of total albuterol sulfate units reimbursed by Medicare from January 1994 through February 1995. These calculations, presented in Appendix C, illustrate the magnitude of potential program savings if Medicare allowances for albuterol sulfate were based on supplier invoice costs.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

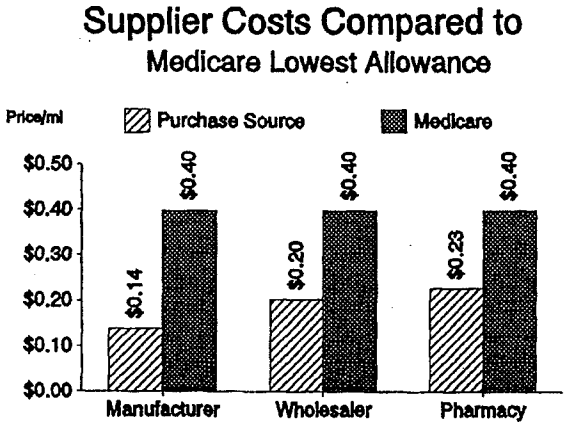
FINDINGS

MEDICARE'S ALLOWANCES FOR ALBUTEROL SULFATE SUBSTANTIALLY EXCEED SUPPLIERS' ACQUISITION COSTS FOR THE DRUG.

- ***Suppliers are paying an average cost of $0.19 per ml for albuterol sulfate.***

During the period of our review, January 1994 through February 1995, Medicare allowed amounts for albuterol sulfate ranged from $0.40 per ml to $0.43 per ml. Clearly, nebulizer drug suppliers' acquisition costs for the drug, averaging $0.19 per ml, are significantly lower than Medicare's AWP-based reimbursements. Medicare allowances for albuterol sulfate, based on a median of national AWPs, totaled over $182 million for this period. If HCFA had based its reimbursement for albuterol sulfate on the average of supplier invoice costs, as collected in our survey, the Medicare program could have saved $94 million during the 14-month period of our review. (See Appendix C) Determination of prescription drug allowances based on EAC--requiring surveys of supplier invoices--is one of the methods presently authorized by Medicare reimbursement regulations.

We estimated an overall average supplier cost for albuterol sulfate of $0.19. Respondents submitted three distinct types of claim-supporting invoices for albuterol sulfate: manufacturer invoices, wholesale company invoices, and pharmacy invoices. These invoices reflect three different purchase sources. Therefore, supplier costs for albuterol sulfate varied widely, ranging from a low of $0.12 to a high of $0.41. To address this variability, we calculated average supplier cost estimates by invoice type. The chart below compares cost estimates per ml for each purchase type to Medicare's lowest reimbursement per ml of albuterol sulfate during the sample period.



- ***When purchased from a drug manufacturer, the average supplier cost per ml of albuterol sulfate was $0.14.***

Thirty-two percent of sampled claims were billed by suppliers who purchased generic albuterol sulfate from a drug manufacturer. In our sample, suppliers' costs paid to the drug manufacturer ranged from $0.12 to $0.17. Medicare's lowest allowance per ml for albuterol sulfate during the sample time frame was $0.40. This allowed amount is almost three times the drug manufacturer invoice price average of $0.14.

- ***The average cost per ml of albuterol sulfate was $0.20 when suppliers purchased the drug from wholesale companies.***

Twenty-three percent of sampled claims were billed by suppliers purchasing the nebulizer drug from wholesalers. While suppliers purchasing from drug manufacturers were able to obtain albuterol sulfate at the most advantageous costs, those paying wholesale costs were reimbursed by the Medicare program at rates at least two times greater than the wholesaler costs estimate.

- ***Suppliers purchasing albuterol sulfate from pharmacies paid an average cost per ml of $0.23.***

Forty-five percent of sampled claims were billed by suppliers who purchased albuterol sulfate from pharmacies. These suppliers received Medicare reimbursements at least 1.8 times greater than the $0.23 pharmacy cost estimate.

Invoices of this type indicate the cost suppliers pay to a pharmacy, not the cost that the pharmacy incurs for the drug. Nebulizer drug suppliers buying albuterol sulfate from pharmacies may be paying for not only the drug, but also the cost of related services provided by pharmacies. These services may include dispensing, packaging and/or shipping the drug to Medicare beneficiaries. Therefore, costs paid by suppliers purchasing the drug from pharmacies were less competitive than those paid to manufacturers and wholesalers.

Only 43 percent of sample claims were billed by suppliers who provided information on their additional costs. Most suppliers did not quantify these other costs per ml of albuterol sulfate. Rather, these suppliers listed general types of additional expenses including sales, billing and support personnel, respiratory therapists, drivers, 24-hour service, home delivery, insurance, and storage. Suppliers also noted expenses such as packaging, labelling, shipping, and delivery of the drug.

- ***Most albuterol sulfate billed to the Medicare program was the generic form of the drug.***

Suppliers submit claims for albuterol sulfate to Medicare under the HCFA Common Procedure Coding System code, J7620. Suppliers bill code J7620 whether the albuterol sulfate they provided to beneficiaries was brand name or generic in form. Our analysis indicates that 90 percent of sampled claims were supported by supplier invoices for generic, non-compounded albuterol sulfate. In contrast, only six percent of sampled claims were supported by supplier invoices for brand name albuterol sulfate.

The remaining four percent of sampled claims were supported by invoices for the ingredients suppliers use to compound albuterol sulfate. Suppliers compound albuterol sulfate on an individual basis from prescribed ingredients. We could not determine unit cost per ml of albuterol sulfate from the compounding ingredient invoices. Therefore, these invoices were not included in the cost analysis.

RECOMMENDATIONS

The findings of this report indicate that Medicare's allowances for albuterol sulfate are excessive compared to suppliers' costs for the drug. During the period of our review, Medicare reimbursed suppliers at allowed amounts ranging from $0.40 to $0.43 per ml of albuterol sulfate. These allowances were based on drug manufacturer AWPs. Current HCFA regulations allow Medicare reimbursement to be based on the lower of EAC or median AWP. However, HCFA has been unsuccessful in gathering the data to determine EAC.

If the HCFA had based its reimbursement for albuterol sulfate on the average of supplier invoice costs, as illustrated in this report, the Medicare program could have saved $94 million during the 14-month period of our review. Although we recognize that suppliers of albuterol sulfate incur other costs related to inhalation therapy in addition to the cost of the drug, we believe current Medicare reimbursements more than compensate suppliers for these costs along with a reasonable profit margin.

We believe our invoice cost analysis further supports a recommendation made in an OIG report entitled *Medicare Payments for Nebulizer Drugs*. We previously recommended that HCFA reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate.

For our readers' convenience, we repeat here the options contained in our prior report for changing Medicare's payments for prescription drugs.

Discounted Wholesale Price

Many Medicaid State agencies use a discounted AWP to establish drug prices. Medicare should have a similar option. Medicare could base its drug payment on the lower of a discounted AWP or the median of the AWP for all generic sources, whichever results in the lower cost to Medicare and its beneficiaries. To implement this recommendation, HCFA would have to revise Medicare's claims coding system which does not identify the manufacturer or indicate if the drug is a brand name or a generic equivalent, information that is needed to discount the AWP and obtain a rebate for a specific drug. Medicaid uses the National Drug Code (NDC) in processing drug claims. The NDC identifies the manufacturer and reflects whether the drug is a brand name or a generic equivalent.

Manufacturers' Rebates

Medicare could develop a legislative proposal to establish a mandated manufacturers' rebate program similar to Medicaid's rebate program. We recognize that HCFA does not have the authority to simply establish a mandated manufacturers' rebate program similar to the program used in Medicaid. Legislation was required to establish the Medicaid rebate program, and would also be required to establish a Medicare rebate

program. We have not thoroughly assessed how a Medicare rebate program might operate, what administrative complexities it might pose, or how a Medicare rebate program might differ from a Medicaid rebate program. We believe, however, the legislative effort would be worthwhile. The same manufacturers that provide rebates to Medicaid make the drugs that are used by Medicare beneficiaries and paid for by the Medicare program.

Competitive Bidding

Medicare could develop a legislative proposal to allow it to take advantage of its market position. While competitive bidding is not appropriate for every aspect of the Medicare program or in every geographic location, we believe that it can be effective in many instances, including the procurement of drugs. Medicare could ask pharmacies to compete for business to provide Medicare beneficiaries with prescription drugs. All types of pharmacies could compete for Medicare business, including independents, chains, and mail-order pharmacies.

Inherent Reasonableness

Since Medicare's guidelines for calculating reasonable charges for drugs result in excessive allowances, the Secretary can use her "inherent reasonableness" authority to set special reasonable charge limits. If this option is selected, however, it will not be effective unless the Secretary's authority to reduce inherently unreasonable payment levels is streamlined. The current inherent reasonableness process is resource intensive and time consuming, often taking two to four years to implement. Medicare faces substantial losses in potential savings--certainly in the millions of dollars--if reduced drug prices cannot be placed into effect quickly.

Acquisition Cost

Medicare could base the payment of drugs on the EAC. The DMERCs currently have this option; however, HCFA has been unsuccessful in gathering the necessary data to fully implement it. Once the problem of gathering the necessary data is overcome, the use of the EAC would result in lower allowed amounts. A variation of this option is to use actual rather than estimated acquisition costs.

HCFA COMMENTS

The HCFA concurred with our recommendation to reexamine Medicare's drug reimbursement methodologies with a goal of reducing payments. In exploring new strategies for changing Medicare's payment for prescription drugs, HCFA has constructed a framework to calculate drug prices centrally. They have also developed a crosswalk between Medicare's current coding system and the NDCs to enable claims processing using the NDC. In addition, HCFA is examining the use of competitive bidding for nebulizers and associated drugs under its demonstration authority.

The HCFA agreed with our concerns about invoking the inherent reasonableness authority and stated that it appreciated the OIG's work in this area. The HCFA is currently addressing this issue through the regulatory process. The full text of HCFA's comments are presented in Appendix D.

In a technical comment, HCFA suggested that we review the proportion of albuterol sulfate actually obtained through a pharmacy as opposed to a pharmacy selling to a DME company who, in turn, sells to the Medicare patient.

OIG RESPONSE

We support HCFA's efforts to revise its drug reimbursement mechanisms to more appropriately pay for prescription drugs covered under the Medicare program. We believe revisions to the current payment methodologies that take into account the actual costs of these drugs would provide significant savings to the Medicare program.

We discussed directly with HCFA staff the data we had available in response to their technical comment.

EXHIBIT 10

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Are Medicare Allowances for Albuterol Sulfate Reasonable?

JUNE GIBBS BROWN
Inspector General

AUGUST 1998
OEI-03-97-00292

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Philadelphia Regional Office prepared this report under the direction of Robert A. Vito, Regional Inspector General and Linda M. Ragone, Deputy Regional Inspector General. Principal OEI staff included:

REGION

Linda M. Ragone, *Project Leader*
Cynthia R. Hansford, *Program Assistant*

HEADQUARTERS

Lisa A. Foley, *Program Specialist*
Stuart R. Wright, *Program Specialist*

To obtain copies of this report, please call the Philadelphia Regional Office at 1-800-531-9562.
Reports are also available on the World Wide Web at our home page address:
http://www.dhhs.gov/progorg/oei

EXECUTIVE SUMMARY

PURPOSE

To determine if the current Medicare allowance for albuterol sulfate is reasonable.

BACKGROUND

Albuterol sulfate is a prescription drug commonly used for inhalation therapy. Medicare allowed $178 million for albuterol sulfate 0.083% in 1996 and over $200 million in 1997.

On January 1, 1998, as a result of the Balanced Budget Act of 1997, Medicare Part B began reimbursing prescription drugs at 95 percent of average wholesale prices. Prior to January 1998, Medicare allowances for drugs were set at the average wholesale price. Medicare allowances include both the Medicare payment and the 20 percent coinsurance amount for which the Medicare beneficiary is responsible.

For albuterol sulfate and other drugs where both brand name and generic versions are available, reimbursement is based on 95 percent of the median average wholesale prices for all generic sources. However, if a brand name product's average wholesale price is lower than the median generic price, a new median including the brand name product must be calculated.

Based on a provision within the Balanced Budget Act of 1997, Medicare can diverge from a statutorily prescribed payment method if its application results in a payment amount that is not inherently reasonable. Another provision of the Act authorizes up to five competitive bidding demonstrations in the Medicare fee-for-service program.

This report provides: (1) information from previously published Office of Inspector General (OIG) reports pertaining to albuterol sulfate, and (2) new updated information on the appropriateness of Medicare allowances for albuterol sulfate.

FINDINGS

Previous OIG reports identified excessive Medicare payments for albuterol sulfate.

- *Medicare and its beneficiaries paid $34 million more than Medicaid for albuterol sulfate in 17 States during a 14-month period ending February 1995.*
- *Supplier acquisition costs are substantially lower than Medicare reimbursement for albuterol sulfate.*
- *Customers of mail-order and retail pharmacies were able to purchase albuterol sulfate for less than what Medicare allowed.*

Current information continues to prove that Medicare and its beneficiaries pay too much for albuterol sulfate.

- *Medicare will allow between 56 to 550 percent more than the Department of Veterans Affairs will pay for generic versions of albuterol sulfate in 1998.*

- *Medicare allowed 20 percent more than the average Medicaid payment for albuterol sulfate in 1997.*

- *Medicare allowed up to 333 percent more than acquisition costs available for albuterol sulfate in 1998.*

- *Customers of mail-order pharmacies will pay up to 30 percent less than Medicare for albuterol sulfate in 1998.*

RECOMMENDATIONS

The findings of this report continue to provide evidence that Medicare and its beneficiaries are making excessive payments for albuterol sulfate. We believe that the information in this report provides further support for recommendations made by the Office of Inspector General. We previously recommended, and HCFA concurred, that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate. We outlined a number of options for implementing this recommendation, including: (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates, and (4) permanent authority to use competitive bidding.

We continue to support the need for a comprehensive statutory reform of Medicare's prescription drug reimbursement methodology. A number of proposals addressing reform have been offered by both the Administration and members of Congress. However, until legislation can be passed providing for such reform, we believe that HCFA should use its inherent reasonableness or competitive bidding authorities to reduce Medicare payments for albuterol sulfate.

The Balanced Budget Act of 1997 provides HCFA with new inherent reasonableness authority that can be applied to most Part B services. Specifically, the statute allows for up to 15 percent annual adjustments in Medicare reimbursement rates without promulgating rules in the Federal Register. Adjustments in excess of 15 percent continue to require promulgation of regulations.

We recommend that HCFA: (1) immediately reduce Medicare reimbursement for albuterol sulfate by 15 percent using the new authority outlined in the Balanced Budget Act of 1997, and (2) consider promulgating rules for a greater reduction in albuterol sulfate reimbursement. A 15 percent reduction in 1997 would have saved Medicare $30 million.

Alternatively, HCFA could use competitive bidding as a method to reduce Medicare payments for albuterol sulfate. The Balanced Budget Act provided HCFA the authority to conduct up to five demonstrations using this approach.

AGENCY COMMENTS

The HCFA concurred with the intent of our recommendations. However, it wants to give Congress the opportunity to act on the Administration's legislative proposal to reduce drug payments before considering the use of its inherent reasonableness authorities. The

TABLE OF CONTENTS

PAGE

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS 6

Previous reports identified excessive payments 6

Current information provides support for a decrease in payments 7

RECOMMENDATIONS 9

APPENDIX A: Health Care Financing Administration Comments . . . . . A - 1

We also were able to collect 1998 drug pricing lists from three wholesale drug companies. The albuterol sulfate 0.083% prices collected are available to pharmacies throughout the nation. There are no additional charges for these drugs.

Pharmacies purchasing drugs from GPOs and wholesalers are sometimes offered additional rebates or discounts based on the amount of drug supplies they purchase. We did not include any volume purchasing discounts or rebates in our pricing calculations.

Mail-Order Pharmacy Prices

We contacted the five mail-order pharmacies surveyed for our earlier report. All five pharmacies were able to provide us with the current 1998 prices they charge their customers for albuterol sulfate 0.083%. Only one pharmacy charged a $1.00 shipping fee per order. This charge was factored into the price. One pharmacy charged a $9.95 membership fee; this amount was not factored into the price.

FINDINGS

PREVIOUS OIG REPORTS IDENTIFIED EXCESSIVE MEDICARE PAYMENTS FOR ALBUTEROL SULFATE.

The Office of Inspector General has issued several reports addressing the appropriateness of Medicare allowances for albuterol sulfate 0.083%. We have compared Medicare's allowance for albuterol sulfate with Medicaid's payments, supplier acquisition costs, and mail-order and retail pharmacy prices. We have found significant differences when comparing what Medicare pays to actual prices available in the marketplace.

Medicare and its beneficiaries paid $34 million more than Medicaid for albuterol sulfate in 17 States during a 14-month period ending February 1995.

Medicare and its beneficiaries would have saved $11 million in payments for albuterol sulfate between January 1, 1994 and February 28, 1995 if reimbursement had been based on Medicaid's payment methodology in the 17 States reviewed. In addition, Medicare would have saved an additional $23 million on albuterol sulfate claims if a drug rebate program similar to Medicaid's had been in place.

Supplier acquisition costs were substantially lower than Medicare reimbursement for albuterol sulfate.

Our review of 230 supplier's actual invoice costs for albuterol sulfate identified an actual average cost of $0.19 per ml of albuterol sulfate during 1994. At the same time, Medicare contractors reimbursed suppliers between $0.40 and $0.43 per ml for albuterol sulfate, more than double the actual cost.

The amounts that suppliers paid for albuterol sulfate varied depending on the type of organization from which the drugs were purchased. When purchased from a drug manufacturer, the average supplier cost was $0.14 per ml. The average cost per ml of albuterol sulfate was $0.20 when suppliers purchased from drug wholesale companies. Suppliers purchasing albuterol sulfate from pharmacies paid an average of $0.23 per ml. Due to a clarification in Medicare policy, suppliers can no longer contract with pharmacies to dispense medication. Only licensed pharmacies can now dispense and bill Medicare for prescription drugs.

Beginning in April of 1995, we surveyed five group purchasing organizations to establish the prices their members pay for albuterol sulfate. These organizations' prices were between $0.13 and $0.19 for generic versions of albuterol sulfate. The thousand of pharmacies that were members of these groups were able to purchase albuterol sulfate at these low prices. At the time of this survey, three DMERCs were paying $0.43 per ml for albuterol sulfate and one DMERC was paying $0.40.

For another report, we reviewed actual wholesale prices available to suppliers in 1995 and 1996 from drug wholesalers and group purchasing organizations. We found that the average actual wholesale price for albuterol sulfate was $0.15 in 1995 and $0.19 in 1996. We found that Medicare and its beneficiaries could have saved 64 percent or an estimated $106 million in 1995 if

payments for albuterol sulfate had been based on average actual costs. In 1996, Medicare and its beneficiaries could have saved 53 percent or $92 million if payments were based on actual costs available to pharmacy suppliers.

Customers of mail-order and retail pharmacies were able to purchase albuterol sulfate for less than what Medicare allowed.

During 1995, we found that five large national mail-order pharmacies charged customers less than Medicare allowed for albuterol sulfate. The companies charged between 2 and 53 percent less than the Medicare allowance of $0.43 per ml of albuterol sulfate. Four of the mail-order pharmacies charged an additional 2 to 20 percent less when a larger volume of drugs were purchased.

During 1995, we also found that 55 percent of retail pharmacy stores surveyed (60 of 109) charged less for the generic version of albuterol sulfate than Medicare allowed. More than one-quarter of the pharmacies charged at least 20 percent less than Medicare for a ml of albuterol sulfate.

CURRENT INFORMATION CONTINUES TO PROVE THAT MEDICARE AND ITS BENEFICIARIES PAY TOO MUCH FOR ALBUTEROL SULFATE.

We updated Medicaid, acquisition, and mail-order prices for albuterol sulfate in 1997 and 1998. We are also providing a comparison of Medicare's reimbursement for albuterol sulfate with that of another Federal agency that procures prescription drugs, the Department of Veterans Affairs.

For most of 1997, Medicare allowed $0.41 per ml or $0.49 per mg for albuterol sulfate 0.083% in unit dose form. Beginning in January of 1998, Medicare allowances for albuterol sulfate are $0.39 per ml or $0.47 per mg of albuterol sulfate in unit dose form.

Medicare will allow between 56 to 550 percent more than the Department of Veterans Affairs will pay for generic versions of albuterol sulfate in 1998.

While Medicare will allow $0.39 for 1 ml of albuterol sulfate in unit dose form, the VA will acquire it for between $0.06 to $0.25 in 1998. We found VA reimbursement for nine generic albuterol sulfate 0.083% products. These products came from six different manufacturers/distributors. The VA can purchase seven of the nine drugs for between $0.06 to $0.12 per ml. The VA pays $0.19 and $0.25 for the remaining two products.

Medicare allowed 20 percent more than the average Medicaid payment for albuterol sulfate in 1997.

In the first three quarters of 1997, the Medicaid program paid an average of $0.34 for a ml of generic albuterol sulfate. Generic products represented 95 percent of the total drug reimbursement for albuterol sulfate in the Medicaid program. During that same time, Medicare paid $0.07 more or 20 percent more per ml than Medicaid. In addition, Medicaid received an average drug rebate of $0.01 for every ml of albuterol sulfate paid for by the program.

Medicare allowed up to 333 percent more than acquisition costs available for albuterol sulfate in 1998.

During 1998, five group purchasing organizations negotiated prices for their members of between $0.10 and $0.19 per ml of albuterol sulfate 0.083%. We obtained prices for 15 albuterol sulfate products from these group purchasing organizations. Fourteen of the 15 prices were between $0.10 to $0.12 per ml.

Three drug wholesalers provided albuterol sulfate to customers for between $0.09 and $0.14 per ml in 1998. We collected nine different product prices from drug wholesalers. The drug wholesalers charged $0.09 for four products and $0.14 for another three products. They charged $0.10 and $0.13 for the remaining two products.

To the pharmacies purchasing albuterol sulfate at these prices, the Medicare program would have allowed between two and four times the acquisition cost of the drug.

Customers of mail-order pharmacies will pay up to 30 percent less than Medicare for albuterol sulfate in 1998.

To provide updated 1998 information, we surveyed the five mail-order pharmacies we reviewed in 1995. Four mail-order pharmacies charged their customers less than Medicare. These pharmacies charged between $0.27 and $0.38 per ml of albuterol sulfate compared with the $0.39 allowed by Medicare. The fifth pharmacy charged between $0.31 and $0.39 depending on the volume of the product purchased.

RECOMMENDATIONS

The findings of this report continue to provide evidence that Medicare and its beneficiaries are making excessive payments for albuterol sulfate. We believe that the information in this report provides further support for recommendations made by the Office of Inspector General. We previously recommended, and HCFA concurred, that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate. We outlined a number of options for implementing this recommendation, including: (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates, and (4) permanent authority to use competitive bidding.

We continue to support the need for a comprehensive statutory reform of Medicare's prescription drug reimbursement methodology. A number of proposals addressing reform have been offered by both the Administration and members of Congress. However, until legislation can be passed providing for such reform, we believe that HCFA should use its inherent reasonableness or competitive bidding authorities to reduce Medicare payments for albuterol sulfate.

The Balanced Budget Act of 1997 provides HCFA with new inherent reasonableness authority that can be applied to most Part B services. Specifically, the statute allows for up to 15 percent annual adjustments in Medicare reimbursement rates without promulgating rules in the Federal Register. Adjustments in excess of 15 percent continue to require promulgation of regulations.

We recommend that HCFA: (1) immediately reduce Medicare reimbursement for albuterol sulfate by 15 percent using the new authority outlined in the Balanced Budget Act of 1997, and (2) consider promulgating rules for a greater reduction in albuterol sulfate reimbursement. We estimate that a 15 percent reduction in albuterol sulfate reimbursement could have saved Medicare and its beneficiaries $30 million in 1997.

Alternatively, HCFA could use competitive bidding as a method to reduce Medicare payments for albuterol sulfate. The Balanced Budget Act provided HCFA the authority to conduct up to five demonstrations using this approach.

AGENCY COMMENTS

The HCFA concurred with the intent of our recommendations. However, it wants to give Congress the opportunity to act on the Administration's legislative proposal to reduce drug payments before considering the use of its inherent reasonableness authorities. The Administration's fiscal year 1999 budget proposes to eliminate the overpayment on outpatient drugs by reimbursing physicians and suppliers at their acquisition costs. The full text of HCFA's comments are provided in Appendix A.

OIG RESPONSE

We support the need for a comprehensive legislative solution to Medicare's drug reimbursement methodology. However, until legislation is passed, we believe that HCFA should utilize the authority recently provided by Congress to take an immediate 15 percent reduction in albuterol sulfate reimbursement.